Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 10 December 2020

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	15 December 2020
2. Schedule 1, items 1 and 2	Immediately after the commencement of Schedule 2 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.	25 February 2021
3. Schedule 1, items 3 to 10	The day after this instrument is registered.	15 December 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989.*

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 2 of Schedule 4 (table item 2.14)

Omit "25 February 2021", substitute "25 August 2021".

2 Part 2 of Schedule 4 (at the end of the table)

Add:

2.15	Medical device that is clinical decision support system software that is: (a) intended by its manufacturer to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and (b) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and (c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times. (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*. (d) The manufacturer of the device must, at all times, have available: (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or (ii) information relating to changes to the device and quality management system. (e) The manufacturer of the device must allow an authorised person to do any of the following: (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device; (ii) inspect the premises and the device, and examine, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device; (iii) make any still or moving image or any recording of those premises or anything on those premises. (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents. (g) The Secretary must not have directed that the

supply of the device be stopped or should cease because the supply compromises public health and safety.

(h) The manufacturer or sponsor of the device must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods:

(i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence;

(ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence;

(iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence;

(iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information.

(i) The sponsor of the device must notify the Secretary, using a form approved in writing by the Secretary:

(i) as far as it is reasonably practicable, of any supply of the device by or on behalf of the sponsor that occurred before 25 February 2021, being a notification within 60 working days (or such longer period as is agreed to by the Secretary) of that day; and

(ii) of any importation or supply of the device by or on behalf of the sponsor on or after 25 February 2021, being a notification within 20 working days (or such longer period as is agreed to by the Secretary) of the importation or supply.

Therapeutic Goods Regulations 1990

3 Subregulation 12B(1B) (table items 10 and 11)

Omit “cholecalciferol”, substitute “colecalciferol”.

4 Subregulation 12B(1B) (table item 18)

Omit “cyclosporin”, substitute “ciclosporin”.

5 Subregulation 12B(1B) (after table item 42)

Insert:

42A	ketotifen	tablet	oral	treatment of allergic conditions

6 Subregulation 12B(1B) (table item 47)

Repeal the item.

7 Subregulation 12B(1B) (table items 73 and 74)

Repeal the items.

8 Subregulation 12B(1B) (after table item 78)

Insert:

78A	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
78B	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed

9 Paragraph 45(7)(b)

Omit "31 December 2020", substitute "31 December 2021".

10 Schedule 4 (table item 8, paragraph (d))

Repeal the paragraph, substitute:

(d) the indications proposed by the sponsor of the medicine are either:

(i) uses of the medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or

(ii) uses of the medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; and